REMARKS

Applicants respectfully request an Interview with the Examiner.

Claim 1 is amended herein by incorporating the subject matter of claims 2 and 3 and claims 2 and 3 are canceled. Claims 12 and 13 are added as new claims. Support is found, for example, at pages 3-4. No new matter is presented.

In response to the rejections set for the in the Final Office Action dated June 11, 2007 and the Examiner's comments in the Advisory Action dated October 3, 2007, Applicants refer to the Amendment filed September 11, 2007 and the Amendment and the arguments presented therein and the Amendment and Request for Reconsideration filed November 2, 2007 and the arguments presented therein, which are incorporated herein in their entirety by reference.

Notwithstanding the above and without conceding the merits of the rejections, claim 1 is amended herein to recite a liquid pharmaceutical composition comprising 5-methyl-1-phenyl-2-(1H)-pyridone (Pirfenidone) or a pharmaceutically acceptable salt thereof and a solvent capable of dissolving said 5-methyl-1-phenyl-2-(1H)-pyridone (Pirfenidone) in a concentration of 10% to about 25% by weight, wherein said solvent is diethylene glycol monoethyl ether (DGME).

None of the references of record specifically disclose, teach or suggest the presently claimed composition, whether taken alone or in combination.

As previously noted, Scheiwe et al discloses that the amount of the active ingredient, i.e., pirfenidone, is preferably within the range of about 0.5% to about 9% by weight, preferably from about 3% to about 7% by weight of the entire composition. Column 2, lines 31-37. Thus, the range taught by Scheiwe et al is <u>not</u> within or close to the presently claimed range.

Although Margolin mentions various preparations including pirfenidone, Margolin does not specifically disclose, teach or suggest a liquid pharmaceutical composition comprising 10 to 25% pirfenidone and DGME. Further, Margolin does not provide any examples or a teaching of how to make any of the dosage forms named, nor any components or ingredients necessary to make such preparations. Margolin also does not recognize the problems associated with obtaining a liquid composition having a high concentration of pirfenidone with the presently recited range. Thus, Margolin is not enabling for one of ordinary skill in the art to make and/or use a liquid composition comprising pirfenidone within the presently claimed range. This is further discussed in the attached Declaration of Dr. Pyare Seth.

Iyer et al does not even disclose, teach or suggest a liquid composition comprising pirfenidone. Iyer et al teaches gelatin capsules comprising loratidine. Iyer et al specifically describes a formulation of loratidine, solubilized in a mixture of solvent and emulsifiers which is specifically to be used in making soft gelatin capsules of this particular drug.

Additionally, there is no apparent reason for one of ordinary skill in the art to combine the references with a reasonable expectation of success in achieving the present invention. Even if combined the present invention would not have been achieved since none of the references teaches the recited concentration of pirfenidone and DGME as a solvent. For at least this reason the present invention is not anticipated nor rendered obvious. Further, none of the references recognizes the problem of obtaining a liquid composition having a high concentration of pirfenidone within the claimed range. Thus, the presently claimed invention would not have been obvious.

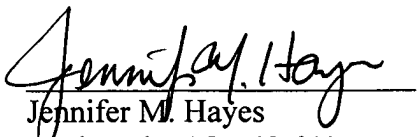
Even further, the present invention provides unexpectedly superior results due to the combination of pirfenidone and DGME, including (1) good stability; (2) lack of skin irritation; and (3) clinical safety. Prior to the present invention, the highest possible concentration of pirfenidone, reportedly dissolved is 7% without recrystallization. Also, previous attempts to make more concentrated liquid formulations containing pirfenidone using alcohol-based solvents have failed and the solvents used irritate the mucous membrane resulting in open wounds as mentioned in the present specification at pages 2-3 and in the attached Declaration under 37 C.F.R. § 1.132 of Dr. Pyare Seth. Thus, the present invention is patentable over the cited references which do not even recognize the problems associated with making an acceptable pharmaceutical composition comprising pirfenidone in high concentrations and which do not recognize the advantageous effects of the combination of pirfenidone and DGME.

Accordingly, Applicants respectfully request withdrawal of the rejections.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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Date: December 11, 2007